

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

LINDA LINGLE GOVERNOR OF HAWAII

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December 10, 2003

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF) CERTIFICATE OF NEED) APPLICATION) NO. 03-32
Kona Community Hospital)
Applicant))) DECISION ON THE MERITS

DECISION ON THE MERITS

The State Health Planning and Development Agency (hereinafter "Agency"), having taken into consideration all of the records pertaining to Certificate of Need Application No. 03-32 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Hawaii County Subarea Health Planning Council and the Certificate of Need Review Panel, hereby makes its Decision on the Merits, including findings of fact, conclusions of law, order, and written notice on Certificate of Need Application No. 03-32.

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BACKGROUND

- 1. This is an application for a Certificate of Need ("Cert.") for the establishment of radiation therapy services at 79-1019 Haukapila Street, Kealakekua, HI at a capital cost of \$4,000,000.
- 2. The applicant Kona Community Hospital is a public corporation organized pursuant to the laws of the State of Hawaii.

- 3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).
- 4. On September 17, 2003, the applicant filed with the Agency a Certificate of Need application for the establishment of radiation therapy services at 79-1019 Haukapila Street, Kealakekua, HI at a capital cost of \$4,000,000 (the "Proposal"). On October 6, 2003, the Agency determined that the application was incomplete and requested additional information. On October 14, 2003 and October 17, 2003, the applicant submitted additional information. On October 21, 2003 the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #03-32.
- 5. The period for Agency review of the application commenced on October 28, 2003, the day notice was provided to the public pursuant to 11-186-39 HAR.
- 6. The Hawaii County Subarea Health Planning Council met at a public meeting on November 5, 2003 and recommended approval of the Proposal by a vote of 7 in favor and none opposed.
- 7. The application was reviewed by the Certificate of Need Review Panel ("Panel") at a public meeting on November 20, 2003. The Panel recommended approval of the Proposal by a vote of 7 in favor and none opposed.
- 8. The Statewide Health Coordinating Council review of the application was waived pursuant to Section 323D-44.6 HRS.
- 9. This application was reviewed in accordance with Section 11-186-15, HAR:
- "(a) The agency shall consider the following criteria in the review of an application for a certificate of need:
 - (1) The need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, are likely to have access to those services;
 - (2) In the case of reduction or elimination of a service, including the relocation of a facility or service:
 - (A) The need that the population presently served has for the service;
 - (B) The extent to which that need will be met adequately by the proposed relocation or by alternative arrangements; and
 - (C) The effect of the reduction, elimination, or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, to obtain needed health care;

- (3) The probable impact of the proposal on the overall costs of health services to the community;
- (4) The probable impact of the proposal on the costs of and charges for providing health services by the applicant;
- (5) The immediate and long term financial feasibility of the proposal;
- (6) The applicant's compliance with federal and state licensure and certification requirements;
- (7) The quality of the health care services proposed;
- (8) In the case of existing health care services or facilities, the quality of care provided by those facilities in the past;
- (9) The relationship of the proposal to the state health services and facilities plan and the annual implementation plan;
- (10) The relationship of the proposal to the existing health care system of the area;
- (11) The availability of less costly or more effective alternative methods of providing service:
- (12) The availability of resources (including health personnel, management personnel, and funds for capital operating needs) for the provision of the services proposed to be provided and the need for alternative uses of these resources as identified by the state health services and facilities plan and the annual implementation plan.
- (b) Criteria for review of an application may vary according to the purpose for which particular review is being conducted or according to the type of health care service being reviewed."
- 10. Pursuant to Section 323D-43(b), HRS:
 - "(b) No Certificate shall be issued unless the Agency has determined that:
 - (1) There is a public need for the facility or service; and
 - (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs."
- 11. Burden of proof. Section 11-186-42, HAR, provides:
 - "The applicant for a certificate of need or for an exemption from certificate of need requirements shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence."

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FINDINGS OF FACT

A. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE STATE PLAN (H2P2)

Vision and Guiding Principles (Chapter II)

- 12. In relation to the goals of H2P2, the applicant states that "The first goal under this section of the H2P2 is to 'increase the span of healthy life for Hawai'i's residents.' The establishment of this radiation therapy unit will cure an undetermined number of cancer patients, thus increasing their life span."
- 13. With respect to the objectives of H2P2, the applicant states that, through the remission of cancer and the provision of palliative radiation therapy treatment, the Proposal will help to reduce the effects of chronic disease, reduce morbidly and prolong health related quality of life.
- 14. In relation to the H2P2 capacity thresholds radiation therapy services, the applicant states:

"The plan contains the following threshold: 'For a new unit/service, all other providers in the service area have averaged a minimum utilization of 8000 procedures and 320 patients per year ...' In this case, the only provider of radiation therapy service in the service area (the Island of Hawai'i) is Hilo Medical Center, which is already providing 9000 procedures per year (SHPDA Utilization Report for 2002, Table 9, page 49). Therefore, this proposal is consistent with this H2P2 standard.

The plan's standard continues '... and the new unit/service is projected to achieve a minimum of 6000 procedures by the third year of operation.' In this case, Kona Community Hospital has used conservative projections for evaluating a 'worst case' financial scenario. Under these projections, we are predicting 4,850 procedures in year 3. If you use the national averages the estimate is 6080 procedures at year 3... We fully expect them to be higher, and exceed the 6,000 threshold, but maintain the conservative projections for financial reasons."

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Statewide and Regional Values and Priorities (Chapter III)

15. With respect to the statewide priorities of H2P2, the applicant states:

"Statewide priorities in the H2P2 include: a. 'Increase access to costeffective health care services...' b. 'Foster the development of care delivery systems for the elderly and chronically ill populations to provide effective management of their health and quality of life and in turn significantly reduce the heavy financial and social burden to their families and to the community.'

The establishment of radiation therapy in West Hawai'i will increase access to these services for West Hawai'i patients, most of whom will be elderly and chronically ill. It will also decrease the financial and social burden to the patients and their families of having to leave the community for weeks of service at another location."

16. In relation to the regional priorities of H2P2, the applicant states the Proposal will address one of the perceived gaps in the Hawai'i County subarea by enhancing oncology services in the community.

Diseases and Conditions (Chapters IV-XI)

- 17. The applicant states that its Proposal addresses the primary goals, community specific issues as well as the process measures CAP-5.2 and CAP-6 of Chapter V (Cancer) of H2P2.
- 18. The Agency finds that this criterion has been met.

B. REGARDING NEED AND ACCESSIBILITY CRITERIA

- 19. The applicant states that "The nearest radiation therapy service is at Hilo Medical Center outside the applicant's catchment area, but still on the same island. It reports 9000 procedures in 2002, and the radiation oncologist there reports that he is unable to accept all referrals."
- 20. The applicant states that the H2P2 "contains the following utilization threshold: 'For a new unit /service, all other providers in the service area have averaged a minimum utilization of 8000 procedures and 320 patients per year ... In this case, the only provider of radiation therapy service in the service area (the Island of Hawai'i) is Hilo Medical Center, which is already providing 9000 procedures per year (SHPDA Utilization Report for 2002, Table 9, page 49)."

- 21. The applicant projects that based upon the population of the Kona Community Hospital's catchment area, the American Cancer Society's incidence of new cancer cases and the Hilo Medical Center's data regarding the number of treatments per patient, the proposed service will perform 4080 procedures in the first year of operation.
- 22. At page II-7 of H2P2, the utilization threshold guideline for radiation therapy further provides that "...the new unit/service is projected to achieve a minimum of 6000 procedures by the third year of operation."
- 23. The applicant states that "In this case, Kona Community Hospital has used conservative projections for evaluating a 'worst case' financial scenario. Under these projections, we are predicting 4,850 procedures in year 3. If you use the national averages the estimate is 6080 procedures at year 3... We fully expect them to be higher, and exceed the 6,000 threshold, but maintain the conservative projections for financial reasons."
- 24. The applicant states that "Kona Community Hospital makes its services accessible to all members of the community. We are the 'safety net' hospital of West Hawai'i and turn away nobody who needs care, without regard to financial status or any other characteristic of the person. We have staff, programs and facilities designed to make our services accessible to minority groups, the elderly, the handicapped and other groups."
- 25. The Agency finds that the need and access criteria have been met.

C. REGARDING QUALITY AND LICENSURE CRITERIA

- 26. The applicant states that it is licensed by the State of Hawaii and certified by Medicare. The applicant further states that it will seek and maintain a Radiation Facility license for the proposed service.
- 27. The applicant states that "The hospital has a long track record of providing high quality services to its community and is accredited by the Joint Commission for the Accreditation of Healthcare Organizations."
- 28. The applicant states that "The professional component of the service will be provided by Hawaii Island Radiation Oncology (HIRO). The physician in HIRO is Dr. James Lambeth, who has provided radiation oncology service at Hilo Medical Center since 1976... He has continuously been certified by the American Board of Radiology (including radiation oncology) and was re-certified in radiation oncology in 1999."

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- 29. The applicant states that "the service will be staff (sic) by 1 FTE radiation oncologist, .5 FTE dosimetrist and .5 FTE physicist. These personnel will be supplied through a contract with Hawaii Island Radiation Oncology. The service will also have 2 FTE therapists and 1 FTE receptionist. We anticipate that these personnel will be provided by the hospital."
- 30. The applicant states that "The radiation oncologist must have: (a) completed a radiation oncology residency in an American Council of Graduate Medical Education (ACGME) program; or, (b) certification in Radiology by the American Board of Radiology (ABR) of a physician who confines his /her professional practice to radiation oncology or certification in Radiation Oncology or Therapeutic Radiology by the ABR, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medicins du Quebec. The radiation therapists must fulfill state licensing requirements and have American Registry Radiologic Technology (AART) certification in radiation therapy. The dosimetrist will be a radiation oncologist, a qualified medical physicist or a radiation therapist with dosimetry training as authorized and supervised by a qualified medical physicist. The medical physicist will be qualified according to the recommendations of the American College of Radiology (ACR)."
- 31. The applicant states that quality assurance provisions will be used to monitor and evaluate the quality of care at the proposed facility and there will be continuing education programs that will be provided for the staff in accordance with the ACR Standard for Continuing Education.
- 32. The Agency finds that quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

- 33. The applicant states that "The project will cost approximately \$4 million. The Hospital Foundation has pledged \$1.5 million of that total. The project will begin with a \$4 million loan and the Foundation's contribution will be used in \$500,000 installments over the first 3 years to insure a positive cash flow with the project."
- 34. The applicant states that "This project will decrease the cost of health care for the citizens of West Hawaii. No longer will they be required to travel to another island, state or city to receive this care. More importantly those who could not afford to obtain this care because of the travel and lodging costs will now have it available."

- 35. The applicant projects operating losses of \$497,600, \$448,700 and \$368,600 respectively, for the first three years of operations. The applicant states that the \$1,500,000 donation from the hospital foundation will be used to offset these losses. The applicant projects operating surpluses of \$70,800 and \$117,300 respectively, for Year 4 and Year 5 of the Proposal.
- 36. The Agency finds that cost and financial criteria have been met.

E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA

- 37. The applicant states that "This project will fill a major gap in the health care delivery system the absence of radiation therapy service for West Hawai'i."
- 38. The applicant states that "In the case of HMC (Hilo Medical Center), there will be an easing of the congestion the facility is now experiencing as its radiation therapy unit approaches its optimum capacity."
- 39. The applicant states that "... since Hilo and Kona are sister facilities under HHSC, there is easy sharing of information and experience. Further, the professional services at both facilities will be provided by Hawaii Island Radiation Oncology, so there will be easy sharing of staff and information."
- 40. The Agency finds that this criterion has been met.

F. REGARDING THE AVAILABILTY OF RESOURCES

- 41. With respect to personnel resources, the applicant states that "the service will be staff (sic) by 1 FTE radiation oncologist, .5 FTE dosimetrist and .5 FTE physicist. These personnel will be supplied through a contract with Hawaii Island Radiation Oncology. The service will also have 2 FTE therapists and 1 FTE receptionist. We anticipate that these personnel will be provided by the hospital."
- 42. With respect to financial resources, the applicant states that the project's capital cost of \$4,000,000 will be financed through a line of credit that the Hawaii Health Systems Corporation has with Academic Capital. The applicant states that the \$1,500,000 donation from the hospital foundation will be used to offset the operating losses projected for the first three years of the Proposal.
- 43. The Agency finds that the applicant has met this criterion.

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CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 03-32 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Hawaii County Subarea Health Planning Council and Certificate of Review Panel, and based upon the findings of fact contained herein, the Agency concludes as follows:

The applicant has met the requisite burden of proof and has shown by a preponderance of the evidence that the Proposal meets the criteria established in Section 11-186-15, HAR.

Accordingly, the Agency hereby determines that, pursuant to Chapter 323D-43(b):

- (1) There is a public need for this proposal; and
- (2) The cost of the proposal will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

ORDER

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a certificate of need to Kona Community Hospital for the proposal described in Certificate Application No. 03-32. The maximum capital expenditure allowed under this approval is \$4,000,000.

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WRITTEN NOTICE

Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 of the Agency's Certificate of Need Program rules. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

DATED: December 10, 2003 Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

David T. Sakamoto, M.D.

Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Decision on the Merits, including findings of fact, conclusions of law, order, and written notice, was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on December 10, 2003.

Ira F. Walton III Chief Executive Officer Kona Community Hospital 79-1019 Haukapila Street Kealakekua, HI 96750

HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

David T. Sakamoto, M.D.

Administrator